

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

REC'D 09 JUN 2006

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2300-21455.4	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/35039	International filing date (day/month/year) 22 October 2004 (22.10.2004)	Priority date (day/month/year) 23 October 2003 (23.10.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 530/350,412,417,421,422;424/234.1,236.1			
Applicant CHIRON CORPORATION			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) ___ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							

Date of submission of the demand 12 May 2005 (12.05.2005)	Date of completion of this report 01 May 2006 (01.05.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	<p>Authorized officer <i>Jennifer E. Graser</i> Jennifer E. Graser</p> <p>Telephone No. 571-272-0500</p>

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:

the international application in the language in which it was filed.

a translation of the international application into English, which is the language of a translation furnished for the purposes of:
 

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4(a))
- international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages 1-90 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

the claims:

pages 91-96 as originally filed/furnished  
 pages\* NONE as amended (together with any statement) under Article 19  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

the drawings:

pages 1-26 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_

the claims, Nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_

the claims, Nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application  
 claims Nos. 40-42

because:

the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for said claims Nos. 40-42

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/35039Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)

Claims 3-6, 8-11, 16-18, 20-24, 29-39 and 49-60 YES  
Claims 1, 2, 7, 12-15, 19, 25-28 and 43-48 NO

Inventive Step (IS)

Claims 3-6, 8-11, 16-18, 20-24, 29-39 and 49-60 YES  
Claims 1, 2, 7, 12-15, 19, 25-28 and 43-48 NO

Industrial Applicability (IA)

Claims 1-39 and 43-60 YES  
Claims NONE NO

## 2. Citations and Explanations (Rule 70.7)

Claims 1, 2, 7, 12-15, 19, 25-28 and 43-48 lack novelty under PCT Article 33(2) as being anticipated by PIZZA MARIAGRAZIA et al.

PIZZA MARIAGRAZIA et al. teach compositions comprising substantially integral bARE class proteins and a stabilizing agent which is a zwitterionic agent. Uncharged agents are taught. Pizza et al teach the AB5, LTK63 and LTK 72 proteins. The proteins are analyzed under non-dissociating conditions which differentiate between integral and dissociated bARE class proteins. Immunogenic compositions and methods of treatment are also taught. See entire document.

Claims 1, 2, 7, 12-15, 19, 25-28 and 43-48 lack novelty under PCT Article 33(2) as being anticipated by Pronk et al.

Pronk et al. teach compositions comprising substantially integral bARE class proteins and a stabilizing agent which is a zwitterionic agent. Uncharged agents are taught. Pizza et al teach the AB5, LTK63 and LTK 72 proteins. The proteins are analyzed under non-dissociating conditions which differentiate between integral and dissociated bARE class proteins. Immunogenic compositions and methods of treatment are also taught. See entire document.

Claims 3-6, 8-11, 16-18, 20-24, 29-39 and 49-60 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the use of stabilizing agents which are a charged amino acid or analog thereof, more specifically arginine or arginine phosphate. Separation steps on a charged polymeric separation material are also not taught.

Claims 1-60 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

*NONE*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:  
C07K 14/195( 2006.01),14/245( 2006.01);A61K 39/39( 2006.01),39/02( 2006.01);G01N 33/483( 2006.01)  
C07K 14/195( 2006.01),14/245( 2006.01);A61K 39/39( 2006.01),39/02( 2006.01);G01N 33/483( 2006.01)

## PATENT COOPERATION TREATY

## PCT

## NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No.	Applicant's or agent's file reference	Date of informal communication (day/month/year)
PCT/US04/35039	2300-21455.4	16 May 2006 (16.05.2006)
Applicant CHIRON CORPORATION		

<u>Communication</u>	<u>Participants</u>	<input checked="" type="checkbox"/> Identity checked	<input checked="" type="checkbox"/> authorization checked	<input type="checkbox"/> personally known
<input checked="" type="checkbox"/> by telephone	<input checked="" type="checkbox"/> Applicant: CHIRON CORPORATION			
<input type="checkbox"/> personal	<input checked="" type="checkbox"/> Agent: Rebecca Hale			
	<input checked="" type="checkbox"/> Examiner(s): Jennifer E. Graser			

Summary of communication:

Informed Applicant that a 409 would be done in lieu of a 408 given the date of the Application.

An extension of time limit is granted (Form PCT/IPEA/427).

A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jennifer E. Graser Telephone No. 571-272-0500
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Form PCT/IPEA/428 (July 1992)